



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,352	03/21/2001	Luis Lopez-Molina	2312-109	3472

6449 7590 12/17/2003

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,352	Applicant(s) LOPEZ-MOLINA ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 32-38 is/are pending in the application.
 4a) Of the above claim(s) 1-24 and 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1638

DETAILED ACTION

The Amendment filed September 17, 2003 has been entered.

Claims 25-29 are newly amended.

Claims 30-31 are cancelled.

Claims 37-38 are newly added.

Claims 1-29 and 32-38 are pending.

Claims 1-24 and 32-36 are withdrawn from consideration.

Claims 25-29 and 37-38 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed December 18, 2002, Paper No. 9, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25, and claims dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

Art Unit: 1638

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 25 as amended is directed to a seed, seedling or plant comprising a polynucleotide which comprises a heterologous promoter operatively linked to a nucleic acid encoding ABI5. The limitation "heterologous promoter" does not find support in the specification as originally filed and thus constitutes new matter.

Claims 25-29 and 37-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a seed, seedling or plant transformed with and expressing an isolated polynucleotide which comprises a constitutive promoter operatively linked to a nucleic acid encoding ABI5, does not reasonably provide enablement for a seed, seedling or plant transformed with but not expressing *ABI5*, or a seed, seedling or plant transformed with and expressing an isolated polynucleotide which comprises a nonconstitutive heterologous promoter, or an inducible or derepressible promoter, operatively linked to a nucleic acid encoding ABI5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a seed, seedling or plant comprising a polynucleotide which comprises a heterologous promoter operatively linked to a nucleic acid encoding ABI5, including a seed, seedling or plant that overproduces ABI5, and a seed, seedling or plant that is hypersensitive to abscisic acid. The claims are also drawn to a seed, seedling or plant comprising

Art Unit: 1638

a polynucleotide which comprises a constitutive, inducible or derepressible promoter operatively linked to a nucleic acid encoding ABI5.

The specification discloses *Arabidopsis* plants transformed with an *ABI5* polynucleotide obtained from *Arabidopsis* (GenBank Accession AC006921) encoding the *Arabidopsis* ABI5 polypeptide expressed under the control of a constitutive CaMV 35S promoter (page 15). In the absence of abscisic acid, *Arabidopsis* plants expressing *ABI5* exhibit ABI5 levels five times greater than the ABI5 levels of nontransformed abscisic acid induced *Arabidopsis* plants (page 15). Germination of *Arabidopsis* seeds expressing *ABI5* also exhibit increased sensitivity to abscisic acid induced inhibition of seed germination and root growth relative to nontransformed *Arabidopsis* plants (page 15, Figure 5A and Figure 5B). The specification does not disclose how to make and use plants transformed with but not expressing *ABI5*, or how to make and use plants transformed with *ABI5* operatively linked to a nonconstitutive heterologous promoter, or to an inducible or derepressible promoter.

While one of skill in the art could readily make a seed, seedling or plant transgenic for *ABI5* operatively linked to a heterologous promoter, it would require undue experimentation for one skilled in the art to determine how to make and use a seed, seedling or plant transgenic for but not expressing *ABI5* operatively linked to a heterologous promoter, because a polynucleotide operatively linked to a promoter would ordinarily be expressed from that promoter. The specification does not provide any guidance with respect to how to prevent expression of *ABI5* from a promoter to which it is operatively linked in a plant transformed therewith. The specification also does not provide any guidance with respect to how to use a transgenic plant that does not express *ABI5* from a promoter to which it is operatively linked.

Art Unit: 1638

Additionally, while one of skill in the art could readily make a seed, seedling or plant transgenic for *ABI5* operatively linked to a nonconstitutive, inducible or derepressible promoter, it would require undue experimentation for one skilled in the art to determine how to make and use a seed, seedling or plant transgenic for and expressing *ABI5* operatively linked to a nonconstitutive, inducible or derepressible promoter, because the timing and location of gene expression from nonconstitutive promoters differs from that of constitutive promoters, and varies among different nonconstitutive promoters. Similarly, the timing and location of gene expression from inducible or derepressible promoters differs from that of constitutive promoters.

Nonconstitutive promoters may only be active in specific plant tissues, or at specific times in plant development, as compared to constitutive promoters which are generally active in all plant tissues and at all times. The use of such promoters requires guidance with respect to when in plant development, and where in the body of a plant, transcription of a particular transgene should occur to produce a desired effect. The use of such promoters also requires additional guidance concerning which particular promoters would express a particular transgene in an appropriate manner, and which would not. Similarly, while inducible or derepressible promoters may be activated at a predetermined time or in a predetermined location under the appropriate circumstances, the use of such promoters requires guidance with respect to when in plant development, and where in the body of a plant, transcription of a particular transgene should occur to produce a desired effect. The use of such promoters also requires additional guidance concerning which particular inducible or derepressible promoters can be activated to express a particular transgene in an appropriate manner, and which cannot.

Art Unit: 1638

Furthermore, abscisic acid levels are known to vary between different plant parts, between different plant developmental stages, and under different environmental conditions. Given that the timing and location of gene expression from nonconstitutive, inducible and derepressible promoters varies, and given that abscisic acid levels also vary, it is unpredictable how a seed, seedling or plant would be affected by expressing at different times and in different locations a protein such as ABI5 whose activity is affected by abscisic acid.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 3, 2003

Phuong Bui
12/11/03